UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: ***Carolyn Lewis, et al. v. Johnson & Johnson, et al.*** ***Case No.: 2:12-cv-04301***	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE BRUCE ROSENZWEIG, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson submit this memorandum in support of their motion to exclude the testimony Bruce Rosenzweig, M.D. in its entirety. Dr. Rosenzweig is a pelvic surgeon and urogynecologist in Ohio who has experience implanting and removing sling systems. Plaintiffs hope to elicit testimony from Dr. Rosenzweig that is well beyond his expertise, such as opinions related to product design, warnings, and the knowledge and state of mind of the parties. For the reasons set forth below, the Court should exercise its gatekeeping role and preclude Dr. Rosenzweig from testifying at trial.

BACKGROUND

Dr. Rosenzweig is a practicing urogynecologist in Cleveland, Ohio. *See* Rosenzweig CV, Exh. A. Even though he is not a materials scientist and has no experience in researching or testing the mesh material, the majority of his opinions are grounded in his conclusions regarding biomaterial aspects of the mesh. Dr. Rosenzweig seeks to offer seven opinions in this case.

A. That the Prolene mesh which comprises the TVT is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence and the IFU was inadequate;

B. That the IFU "did not disclose information to physicians in its IFUs regarding characteristics of the polypropylene in Ethicon's TVT mesh (Prolene) that make it unsuitable for its intended application as a permanent prosthetic implant";

C. That Ethicon did not adequate describe how to "tension" the device and "inform them that improper tension on the mesh decreased effective pore size and interfered with incorporation into tissue";

D. That Ethicon "did not inform physicians and their patients that Manufacturer Safety Data Sheets (MSDSs) for polypropylene resin used to manufacturer polypropylene meshes warned against use of the mesh in a permanently implanted medical device and that studies showed that it caused sarcomas in laboratory rats";

E. That Ethicon did not inform physicians that "toxicity testing of the polypropylene mesh revealed that it was cytotoxic";

F. That the promotional materials were inaccurate or inadequate;

G. That the patient brochures were inaccurate or inadequate.

Exh. B, Rosenzweig Report ("Report"), at 3. Dr. Rosenzweig should not be permitted to render opinions grounded in alleged design defect, opinions A-C, because he lacks qualifications and the opinions do not "fit" this case. Moreover, his opinion D regarding the MSDS and sarcoma in laboratory rats is unsupported, irrelevant, and extremely prejudicial to Defendants. Opinion E, regarding cytotoxicity, is without reliable basis, as Dr. Rosenzweig has shown no greater expert methodology than lifting a portion of an Ethicon document out of context. Finally, his opinions regarding the IFU (appearing throughout), promotional materials (opinion F), and patient brochures (opinion G) are all irrelevant, as the undisputed evidence shows that Dr. Boreham and Mrs. Lewis did not rely on these materials in their decision to implant the TVT. Dr. Rosenzweig's opinions should therefore be excluded in their entirety.

ARGUMENT

I. Dr. Rosenzweig's Design Opinions Should Be Excluded.

Dr. Rosenzweig's first three opinions, comprising nearly thirty pages of his Report, are that certain "design characteristics" render TVT unsuitable for use in the treatment of stress urinary incontinence. *See* Report at 12-39. He contends, for example, that polypropylene mesh—such as the PROLENE* Polypropylene Mesh used in TVT—undergoes degradation and particle loss. *Id.* at 13-21, 33-39. He also maintains that TVT is subject to an increased risk of infection because it is implanted transvaginally into a clean-contaminated surgical field. And Dr. Rosenzweig claims that the PROLENE mesh is a "small pore, heavy weight" mesh, the design of which causes a chronic foreign body reaction. *Id.* at 22.

Dr. Rosenzweig should be precluded from offering each of these opinions. Not only is he not qualified to proffer opinions regarding the design characteristics of mesh implants, but Dr. Rosenzweig's opinions are in many respects irrelevant and unreliable.

A. Dr. Rosenzweig's design opinions exceed the scope of his qualifications.

Dr. Rosenzweig reports that the basis for his opinions is his experience as a surgeon. *Id.* at 2. He claims to have performed "over a thousand pelvic floor surgical procedures," including repairs involving Ethicon's TVT, TVT-Obturator, and Prolift, and "over 200 surgeries dealing with complications related to synthetic mesh, including the removal of numerous TVT devices." *Id.* at 2. Yet Dr. Rosenzweig estimated in deposition that he had performed only "15 to 20" implants involving TVT and confirmed that, of the hundreds of explants he has performed, only 25 were "TVT products," meaning TVT or TVT-O. Exh. C, Rosenzweig Dep. at 65:9-16, 71:5-16, 72:2-7. Dr. Rosenzweig's *relevant* experience, therefore, is not nearly as extensive as his Report suggests.

More important, irrespective of the number of surgeries Dr. Rosenzweig has performed, his opinions in this matter extend far beyond the surgical procedures, and he unquestionably lacks the additional experience necessary to offer the specific opinions set forth in his Report. He has never conducted oxidative degradation testing, molecular weight testing, or tensile strength testing to inform his opinion that polypropylene undergoes degradation. *Id.* at 170:2-9, 219:19-222:6. Indeed, when asked the basis for his degradation opinion, he testified that an explanted mesh once "looked really beaten up." *Id.* at 59:6-11. With respect to infection risks, Dr. Rosenzweig confirmed that he has never performed a pathological analysis on any type of mesh. *Id.* Dr. Rosenzweig has never performed any pathological analysis on a removed TVT or implant and has never done bench research or lab research with respect to polypropylene. *Id.* at 60:25-61:4, 56:20-23. He has never published anything about polypropylene, much less concerning its degradation, porosity, cytotoxicity, fibrotic bridging, contracture, or foreign body response. *Id.* at 168:15-8, 208:25-209:2. In fact, he has never performed any research or development with respect to polypropylene at all. *Id.* at 169:6-8. Nevertheless, Dr. Rosenzweig's first three opinions all rest on the design characteristics of the PROLENE mesh, including its purported potential for degradation; weight; pore size; susceptibility for "biofilm formation due to the weave of the mesh"; potential for fibrotic bridging and shrinkage caused by "small mesh pores"; and potential for "particle loss, fraying, roping and curling, loss of pore size." Report at 20, 22, 26, 27, 30, 33.

These opinions all require specialized knowledge in the area of biomaterials and product design. Dr. Rosenzweig has only performed "15 to 20" TVT implants and only 25 TVT or TVT-O removals and has done no relevant research on these design subjects. Dr. Rosenzweig plainly lacks the qualifications to offer these design opinions.

B. Dr. Rosenzweig's opinion that TVT is subject to an increased risk of infection is irrelevant to this case.

Separate and apart from his complete lack of qualifications, Dr. Rosenzweig's opinion that TVT is subject to an increased risk of infection should be excluded because that opinion has no relevance to this case. In *Daubert*, the Supreme Court explained that, in addition to reliability, "Rule 702 further requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue," a requirement that "goes primarily to relevance." *Daubert*, 509 U.S. at 591. In elucidating this "fit" requirement, the Supreme Court noted that scientific expert testimony carries special dangers to the fact-finding process because it "can be both powerful and quite misleading because of the difficulty in evaluating it." *Id.* For that reason, circuit courts have held that proffered scientific evidence must be excluded "under Rules 702 and 403 unless [district courts] are convinced that it speaks *clearly and directly to an issue in dispute in the case*." *Daubert v. Merrell Dow Pharms., Inc.* ("*Daubert II*"), 43 F.3d 1311, 1321 n.17 (9th Cir. 1995) (emphasis added); *see also United States v. Ford*, 481 F.3d 215, 220 n.6 (3d Cir. 2007) ("In particular, district courts should tread carefully when evaluating proffered expert testimony, paying special attention to the relevance prong of *Daubert*.").

Far from speaking "clearly and directly" to an issue in this case, Dr. Rosenzweig's opinion that TVT is subject to an increased risk of infection has absolutely no bearing here, for Mrs. Lewis did not have an infection. Dr. Zimmern, the surgeon who examined Mrs. Lewis and partially removed her TVT device in August 2013, testified that he saw no evidence of an infection and that he never diagnosed Mrs. Lewis with an infection. Exh. D, Excerpts of Oct. 18, 2013 Dep. of Philippe Zimmern, M.D., at 42:4-6. This testimony was confirmed by Dr. Sexton—Ethicon's infectious disease expert and the only board-certified infectious disease doctor in this case—and by Dr. Zheng—Ethicon's expert pathologist. *See* Exh. E, Report of

Daniel J. Sexton, M.D. ("Sexton Specific Report") at 4 (finding "no clinical evidence that the TVT mesh implanted in Mrs. Lewis . . . resulted in a mesh-related infection"); Exh. F, Expert Report of Dr. Wenxin Zheng ("Zheng Report") at 8 ("Mrs. Lewis did not have an infection.").

Because Mrs. Lewis did not have an infection, Dr. Rosenzweig opinion that TVT is subject to an increased risk of infection is irrelevant to this case and will serve only to confuse the issues and mislead the jury. *See Daubert*, 509 U.S. at 591 (warning of risk that expert testimony will mislead the jury). For that reason, Dr. Rosenzweig's opinions regarding infection should be excluded.

C. Dr. Rosenzweig should not be permitted to testify that polypropylene mesh is subject to degradation and particle loss.

As mentioned, Dr. Rosenzweig opines that TVT is defective because it degrades *in vivo* and is subject to fraying or particle loss. *See* Report at 13-21, 33-39. With respect to degradation, Dr. Rosenzweig cites in his Report "peer-reviewed literature regarding degradation/oxidation of polypropylene in the human body [that] dates back to the 1960's." *Id.* at 17. From these studies, Dr. Rosenzweig states his opinion that, "without anti-oxidants to protect the polypropylene *in vivo*, there is a significantly increased risk of oxidation/degradation in a woman's pelvic tissues after implantation of TVT mesh." *Id.* at 19. As for fraying and particle loss, Dr. Rosenzweig references internal Ethicon documents and photos that "clearly show" particle loss, which he believes can lead to an increased inflammatory response and "to a multitude of injuries." *Id.* at 38-39.

Dr. Rosenzweig's opinions regarding degradation and fraying should be excluded because he cannot begin to explain their clinical significance, if any. In his Report, Dr. Rosenzweig spends page after page discussing the causes of degradation. He devotes only a paragraph, however, to its significance, stating that "degradation of the TVT Prolene mesh in a

woman's tissues can lead to a greater foreign body reaction, enhanced inflammatory response and excessive scarring." *Id.* at 20. In his deposition, Dr. Rosenzweig offered the same theory, namely, that when mesh degrades, "you can have particle loss which increases the surface area which increases the chronic foreign body reaction." Exh. C, Rosenzweig Dep. at 67:19-23. Yet Dr. Rosenzweig could not confirm that he has ever treated a patient who suffered from an increased foreign body response directly attributable to particle loss. *Id.* at 67:6-69:9.

Dr. Rosenzweig's inability to testify to the specific implications of degradation and particle loss render his opinions on these subjects irrelevant to this case. Texas law requires that a claimant in a design defect case prove, among other things, that "the defect was a producing cause of the personal injury . . . for which the claimant seeks recovery." *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999). Dr. Rosenzweig believes that the polypropylene mesh used in TVT is defective because it degrades and is subject to particle loss, yet he is unable to correlate these alleged defects to some specific complication. Because Dr. Rosenzweig cannot say with any probability that degradation or particle loss caused Mrs. Lewis' injury, his opinions on these issues are irrelevant to this case and must be excluded. *See Daubert II*, 43 F.3d at 1321 n.17 (observing that proffered scientific evidence must be excluded "under Rules 702 and 403 unless [district courts] are convinced that it speaks clearly and directly to an issue in dispute in the case").

II. Dr. Rosenzweig's Opinions Regarding Cancer Should Be Excluded.

Dr. Rosenzweig opines that "the possibility that polypropylene mesh can cause tumors or cancer is documented" in the MSDS sheets for the polypropylene resin used in the manufacture of PROLENE mesh. Report at 61-62. Dr. Rosenzweig also cites "studies show[ing] that

polypropylene causes sarcomas in laboratory rats." *Id.* at 59. He claims that Ethicon should have warned physicians and their patients about this risk.

Dr. Rosenzweig is not qualified to offer any opinions regarding polypropylene and cancer. As discussed above, Dr. Rosenzweig indicates in his report that his opinions are based on his experience implanting and explanting Ethicon's pelvic mesh devices. Nothing in his experience as a surgeon would inform Dr. Rosenzweig's opinion that polypropylene mesh has been linked to cancer and that Ethicon should have warned of this risk.

Moreover, any opinion regarding cancer is irrelevant to this case and would be extremely prejudicial. It is undisputed that Mrs. Lewis does not have cancer. *See* Exh. G, Pls. Resp. to Defs. 2nd Set of Requests for Admissions, p. 25 (admitting that Mrs. Lewis has never been diagnosed with a mesh-related sarcoma or carcinoma). Nor has any expert witness—including Dr. Rosenzweig—opined to a reasonable degree of medical probability that she will develop mesh-related cancer in the future. As a result, opinions regarding cancer would serve only to confuse the issues and mislead the jury, a very real risk given the subject matter.[1] Put succinctly, it is not reasonable to think that, once the word "cancer" is uttered, the jury could simply disregard or unhear it; the unavoidable prejudice to Defendants is self-evident.

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[1] *See In re: C. R. Bard, Inc.*, 2013 U.S. Dist. LEXIS 90210, *24 (S.D. W.Va. June 27, 2013) (strictly limiting references to cancer and strongly cautioning plaintiffs to "tread carefully" with such evidence); *Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156, 1160 (4th Cir. 1986) (finding that evidence is not admissible to prove damages where there is less than a reasonable probability that plaintiff will actually develop cancer); *see also, e.g.*, *O'Banion v. Owens-Corning Fiberglas Corp.*, 968 F. 2d 1011 (10th Cir. 1992) ("we agree with those courts which have held that evidence of cancer is so prejudicial that, in the absence of expert medical testimony that a 'reasonable degree of medical certainty' exists that the plaintiff will develop cancer, such evidence should be excluded"); greater than fifty-percent chance of contracting asbestos-related cancer in the future); *Gideon v. Johns-Manville Sales Corp.*, 761 F.2d 1129 (5th Cir.1985) (admitting evidence of cancer only after plaintiff proffered expert testimony that a reasonable medical probability existed that he would in fact develop cancer).

Finally, Dr. Rosenzweig's implication that polypropylene is linked to cancer in humans is not based on a reliable methodology. Any implication that polypropylene mesh poses a risk of cancer must be accompanied by a methodologically-appropriate assessment of the scientific studies on this topic. Instead, Dr. Rosenzweig relies on an MSDS sheet and rodent. He does not account for the large body of scientific data demonstrating that carcinogenic effects in rodents are not applicable to humans and that demonstrations of such an effect should come from human studies. *See* Exh. H, Report of Jeffrey Brent, M.D., Ph.D, at 13 (citing literature). And Dr. Rosenzweig ignores the medical literature—including studies authored by Plaintiffs' own experts—that clearly states that polypropylene resin has never been found to cause cancer in humans. *See, e.g.* Exh. I, Klosterhalfen, U. Klinge et al., Meshes: Benefits and Risk; Chap. 24, Foreign-Body Carcinogenesis of Surgical Meshes, 2004 ("Malignancies after implantation of surgical meshes have not been reported in literature since their first description and clinical introduction by Usher in 1958."); Exh. J, B Klosterhalfen, U. Klinge et al., Abdominal Wall Hernias, Chap. 29, Carcinogenicity of Implantable Biomaterials, 2011 ("Fortunately, up to now no example of tumor development after mesh implantation has been documented."); Exh. K, B. Michael Ghadimi, *The carcinogenic potential of biomaterials in hernia surgery,* Chirurg, 2002, 73:833-838 ("In conclusion, there are no data so far indicating a real risk for humans to develop malignant tumors due to implanted meshes."). Under these circumstances, Dr. Rosenzweig's opinion should be excluded as unreliable.

III. Dr. Rosenzweig's Opinion that Polypropylene Mesh is Cytotoxic Should Be Excluded.

In his Report, Dr. Rosenzweig opines that Ethicon did not act as a reasonable medical device manufacturer because it failed to inform physicians and their patients about the risk of cytotoxicity, or the "toxicity to the cells causing cell injury or death." Report at 65. Dr.

Rosenzweig should not be permitted to testify that polypropylene mesh is cytotoxic or that Ethicon should have warned physicians of toxicity testing.

To begin, Dr. Rosenzweig is not qualified to offer these opinions. He testified that he has never conducted toxicity or cytotoxicity testing of polypropylene or any other mesh. Exh. C, Rosenzweig Dep. at 219:19-222:6. Nothing in Dr. Rosenzweig's experience as a urogynecologist and surgeon qualifies him to render such an opinion.

Further, the entirety of his support and methodology for his opinion that the PROLENE mesh is cytotoxic comes from a document produced by Ethicon titled "Cytotoxicity Risk Assessment for the TVT Ulmsten Device" from August 8, 1997. Report at 63. Dr. Rosenzweig's report conspicuously omits the conclusion of the Risk Assessment: "this clinical data provides important evidence that the cytotoxicity of the PP mesh observed in vitro does *not* translate into any clinical significance or adverse patient outcomes." *See* Cytotoxicity Risk Assessment for the TVT Ulmsten Device, Aug. 8, 1997, Exh. L (emphasis added).

The risk assessment cited by Dr. Rosenzweig only shows that in some in vitro tests with the PROLENE mesh cytotoxicity was found, out of the many other in vitro tests where cytotoxicity was not found. In any event, what is more relevant here and in other cases is not what occurs in a petri dish, but what occurs in the human body. Indeed, the risk assessment confirmed that cytotoxicity observed in vitro did not translate into toxicity in human or animals, and Dr. Rosenzweig has failed to identify a single study stating otherwise and provides no reasoned basis to dispute the conclusion of cytotoxicity risk assessment. Further, Dr. Rosenzweig has failed to identify or cite a single article concluding that the Prolene mesh is cytotoxic in humans. His opinion is without reliable basis and should be excluded.

IV. Dr. Rosenzweig's Opinions Regarding the IFU, Promotional Materials, and Patient Brochure Do Not Apply to the Facts of This Case and Should Be Excluded.

Dr. Rosenzweig's opinions regarding the adequacy of the IFU, promotional materials, and patient brochure have no relevance to Mrs. Lewis's claims under Rules 401 and 402. *See* Report at 65-78. Because neither Mrs. Lewis nor her physician relied on the IFU, promotional materials, or patient brochure, these opinions do not relate at all to the issues in dispute in this case.

A. Mrs. Lewis's physician did not rely on the IFU.

Throughout his Report Dr. Rosenzweig criticizes the IFU provided by Defendants for various perceived inadequacies. *See, e.g.*, Sections III.B (Report at 40), III.C (Report at 53), III.D (Report at 54; III.E (Report at 58), and III.F (Report at 64). He finds numerous faults in the IFU, opining that it "did not adequately warn physicians" about various risks. *E.g.*, Report at 27. However, because Dr. Boreham did not rely on the IFU in making her decisions regarding the treatment of Mrs. Lewis, this testimony lacks fit and should be excluded.

Dr. Boreham testified that she had not read Ethicon's instructions for use since her fellowship in 2002. Exh. M, Boreham Dep. Excerpts, 15:16-18, 60:21-24, 218:12-19. She bases her treatment decisions on her knowledge, training and experience, and not on what a manufacturer tells her. *Id.* at 58:23, 216:23-217:21. She testified that her decision to prescribe and use TVT to treat Mrs. Lewis' stress urinary incontinence had nothing to do with the IFU or anything Ethicon said. *Id.* at 218:23-219:2; *see also id.* at 222:9-15 ("That's right, I did not" rely on the IFU in prescribing TVT to Mrs. Lewis).

Under Texas law, in "order to recover for a failure to warn claim under the learned intermediary doctrine, a plaintiff must show: (1) the warning was defective; and (2) the failure to

warn was a producing cause of the plaintiff's condition or injury." *Porterfield v. Ethicon*, 183 F.3d 464, 468 (5th Cir. 1999). Where the implanting physician did not read or rely on the IFU or otherwise knew the risks, the plaintiff has not satisfied her burden to show causation. *See id.* As this Court has held, "there is no proximate cause where a warning—albeit ostensibly inadequate—was never read." *Jones v. C.R. Bard, Inc.* (*In re C. R. Bard, Inc.*), 2013 U.S. Dist. LEXIS 84134, *9 (S.D.W. Va. June 14, 2013) (noting the "vast body of case law among many jurisdictions" so holding).

By the same token, Dr. Rosenzweig's opinions about whether or not the IFU adequately warned about various risks is completely irrelevant when even a "perfect" warning would never have been read by Mrs. Lewis's physician. It would therefore be confusing and misleading to the jury to be presented with expert testimony on the issue.

B. Neither Mrs. Lewis nor her physician relied on the patient brochure or promotional materials cited by Dr. Rosenzweig.

Similarly, Dr. Rosenzweig's opinions about the patient brochure and promotional materials should also be excluded, as they have no connection to Mrs. Lewis's case.

Mrs. Lewis testified that her decision to have a TVT sling was based solely on the medical judgment of Dr. Boreham. Exh. N, Excerpts of Lewis Dep. at 298:3-21. Mrs. Lewis testified that she never received a patient brochure on TVT. *Id.* 71:13-15. She did not rely on any materials provided by Ethicon in having a TVT sling. *Id.* at 71:16-72:6. Similarly, Dr. Boreham testified that she used the TVT product "because it's got more data than almost any other device in history" and that she receives that data not from Ethicon, but from peer reviewed journals and meetings. Exh. M, Boreham Dep. at 57:24-58:6. There is no evidence she relied on any promotional material or brochure received from Ethicon.

Because Mrs. Lewis and her treating physician never relied upon the materials sought to be admitted, Dr. Rosenzweig's opinions are irrelevant and will not assist the jury in any way. For this very reason, in *Hines v. Wyeth*, the court excluded an expert's testimony regarding defendants' marketing strategy where the evidence showed that neither the plaintiff nor her physician testified relied on any marketing materials. 2011 U.S. Dist. LEXIS 74042, *11-12 (S.D. W. Va. July 8, 2011) (Copenhaver, J.). The expert testimony was "wholly irrelevant if plaintiff cannot demonstrate that she personally would have avoided harm had the defendants marketed their drugs more appropriately." *Id.* at *12; *see also Lea v. Wyeth LLC,* 2011 U.S. Dist. LEXIS 155503 (E.D. Tex. Sept. 16, 2011) ("The proffered testimony . . . does not assist the jury in determining a fact at issue are irrelevant and inadmissible" where "[n]either Plaintiff nor Dr. Kirby testified that they relied on Defendants' marketing"); *In re Norplant Contraceptive Prods. Liab. Litig.*, MDL No. 1038, 1997 WL 81092 (E.D. Tex. Feb. 21, 1997) ("[a]bsent evidence that the physicians were exposed to the above listed materials, . . . the promotional materials are not relevant evidence.").

Dr. Rosenzweig's opinions regarding the patient brochures and promotional materials have no connection to this case and thus lack the requisite "fit" required under *Daubert.*

V. Other Improper Testimony.

As stated, the expert opinions of Dr. Rosenzweig should be excluded in their entirety. However, in the event the Court admits any of his testimony, Defendants note that Dr. Rosenzweig's opinions are riddled with other improper testimony which should be excluded.

A. Improper narrative testimony and testimony regarding Ethicon's knowledge, state of mind, and corporate conduct and ethics.

Throughout his Report, Dr. Rosenzweig repeatedly and improperly opines about what "Ethicon knew."[2] This testimony about Ethicon's state of mind is derived exclusively from Dr. Rosenzweig's review of the company documents and depositions taken in this case and exceeds the scope of proper expert testimony.

This testimony about Ethicon's state of mind will "invade the province of the jury rather than assist it in resolving material issues of fact," because it consists entirely of the interpretation of evidence that is within the ken of an ordinary juror. *See Hines*, 2011 U.S. Dist. LEXIS 74042, *11-12; *see also Cisson v. C.R. Bard, Inc.*, 2013 U.S. Dist. LEXIS 78061, *139 (S.D. W. Va. June 4, 2013) (holding that opinions regarding "Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury"). The jury is perfectly capable of reading a document or hearing deposition testimony and does not need the expert's assistance to do so.

[2] *See, e.g.*, Report at 18 ("Ethicon knew degradation of its mesh could occur."); Report at 29 ("Ethicon knew that light weight, large pore mesh could decrease the likelihood of foreign body reaction, fibrotic bridging and scar plating"); Report at 35 ("Ethicon also knew very early on that the TVT mesh would rope, curl and become deformed when under tension"); Report at 36 ("Engineers at Ethicon knew that TVT could cause more urinary retention than some of its other meshes"); Report at 46 ("If you compare the adverse reactions/risks in the TVT IFUs to the adverse reactions/risks Ethicon knew at the time of the launch of TVT, it is clear that there are numerous adverse events absent from the IFU"); Report at 49 ("Ethicon knew of the risks at the time of launch."); Report at 50 ("Ethicon also knew that erosions could occur many years after implantation of the device.); Report at 54 ("Ethicon knew about significant harms and hazards related to the Prolene mesh used in the TVT."); Report at 57 ("Meanwhile, Ethicon knew that patients were suffering from erosions and, in fact, would often blame the physician as the cause of the erosion for putting "too much tension on the device."); Report at 76 ("Ethicon knew of other studies showing a much lower success rate.").

Similarly, Dr. Rosenzweig's personal ethical views are not proper expert testimony. For instance, in his Report, Dr. Rosenzweig deems Ethicon's conduct "unconscionable." Report at 64. He also faults Ethicon because it "never disclosed to physicians the bias and inherent conflict of interest related to the Ulmsten data," even though he identifies no requirement for Ethicon to have done so. Report at 67. These subjective ethical judgments do not constitute "scientific, technical, or other specialized knowledge" as contemplated by Rule 702. *Cisson*, 2013 U.S. Dist. LEXIS 78061 at 38-39 (excluding "corporate conduct and ethics" opinions).[3] Accordingly, Dr. Rosenzweig should be barred from testifying regarding Ethicon's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics.

B. Improper legal opinion.

As this Court has observed, "[t]he questions of whether . . . products were not reasonably safe, for example, or whether [the manufacturer] failed to warn, are questions for the jury, not for [the expert]." *Cisson*, 2013 U.S. Dist. LEXIS 78061 at *90 (excluding opinions such as whether manufacturer "failed to adequately disclose the adverse risks" or "failed to warn on its label"). "[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to

[3] *See also Wolfe v. McNeil-PPC, Inc.*, 2011 U.S. Dist. LEXIS 47710, *26-28 (E.D. Pa. May 3, 2011) (rejecting expert's reliance on "simple common sense and ethical responsibility" and noting that "[s]imply because Dr. Goldberg's subjective views of ethics are informed by well-known principles does not convert them into objective, reliable, scientific knowledge."); *Ingram v. Wyeth, Inc. (In re Prempro Prods. Liab. Litig.)*, 2010 U.S. Dist. LEXIS 142558 (E.D. Ark. Sept. 16, 2010) (excluding expert testimony as "too subjective and not expert in nature" where the experts "would only be able to subjectively testify about what companies could do . . . rather than what [they] were required to do."); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 2010 U.S. Dist. LEXIS 41304, *15 n.3 (M.D. Ga. Apr. 27, 2010) (finding that "Code of Ethics" could be just as easily understood by jurors and thus expert's opinions were "unnecessary"); *In re Fosamax Prods Liab Litig.*, 645 F. Supp. 2d 164, 194 (S.D.N.Y. 2009) (rejecting expert's testimony about ethical standards governing the conduct of clinical trials where expert applied standards such as the virtues of "[t]rust and honesty", finding "such standards are 'so vague as to be unhelpful to a fact-finder'").

the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). Nevertheless, that is exactly what Dr. Rosenzweig seeks to do.

In his Report, Dr. Rosenzweig repeatedly states in various ways that Ethicon failed to warn of the risks.[4] In addition, throughout his Report, Dr. Rosenzweig opines that, in at least 13 different respects, "Ethicon failed to act as a reasonable and prudent medical device manufacturer." *See* Report at 13, 20-21, 23, 26, 30, 32, 39, 53, 54, 58, 64, 66, 79.

Besides the obvious shortcoming that Dr. Rosenzweig did not first articulate what, in his opinion, is the standard of care for a "reasonable and prudent device manufacturer," these opinions are nothing more than improper legal conclusions that invade the province of the judge and jury. They should therefore be excluded.

C. Improper narrative testimony.

Dr. Rosenzweig should not be permitted to regurgitate company documents, exhibits, and other various websites under the guise of expert testimony.

For instance, in describing the company's "knowledge," Dr. Rosenzweig repeatedly (and selectively) quotes from portions of company documents. As stated, this is improper testimony, as the jury does not need an expert to tell them what a document says. More disturbingly, in his Report, Dr. Rosenzweig appears to have lifted large portions from Internet websites, even where there is no connection to the facts of this case at all.

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[4] *See, e.g.*, Report at 3 ("Ethicon failed to adequately describe, inform or explain to physicians how to properly "tension" the TVT and inform them that improper tension on the mesh decreased effective pore size and interfered with incorporation into tissue"); Report at 27 ("[Ethicon] did not adequately warn physicians about these important risks nor, by extension, provide surgeons with an opportunity to discuss these risks with their patients."); Report at 49 ("Ethicon fell below the standard of care required of a reasonable medical device manufacture by failing to adequately disclose these known risks to physicians").

These websites are not the type of facts or data that "experts in the particular field would reasonably rely on," as they are primarily websites directed at laypersons. Fed. R. Evid. 703. For instance, in his section describing "Background and Treatment Options for Stress Urinary Incontinence," Dr. Rosenzweig cites (generally) www.fda.gov and the article "Urinary Incontinence" on Wikipedia, an open-access online encyclopedia that can be edited by anyone with Internet access. Report at 4; *see generally United States v. Lawson*, 677 F.3d 629, 650 (4th Cir. 2012) (describing Wikipedia).[5] Plaintiffs cannot seriously contend that experts in the field of urogynecology rely on such layperson websites in their practice. *See Bing Shun Li v. Holder*, 400 F. App'x 854, 857-58 (5th Cir. 2010) (unpublished) (noting that Wikipedia is "an unreliable source of information" and warning against reliance on it or similarly unreliable internet sources)) (citing *Badasa v. Mukasey*, 540 F.3d 909, 910 (8th Cir. 2008)); *see also TechRadium, Inc. v. Blackboard Connect, Inc.*, No. 2:08-CV-214, 2009 U.S. Dist. LEXIS 36083, at *13 n.5 (E.D. Tex. Apr. 29, 2009) ("Wikipedia disclaims any validity of the content listed on its website, and is therefore not a reliable source of technical information.").

Indeed, in his deposition, Dr. Rosenzweig admitted to copying and pasting portions of such websites into his expert report, even where the information was not pertinent to Mrs. Lewis's claim. Regarding the information in his Report about pubovaginal slings (a type of sling that is not at issue in this case), Dr. Rosenzweig testified:

Q. And that's a section of it looks like seven or eight paragraphs about pubovaginal slings, is that correct?
A. That is correct.
Q. Simply a history of what they are sort of thing?
A. Yes.
Q. And this is approximately eight paragraphs of your 77-page report?
A. That is correct.

[5] In that section, Dr. Rosenzweig also cites such other websites as www.webmd.com, www.netdoctor.com, and www.womensdoctor.com. Report at 5, 7, 8.

Q. Okay. Why did you include those paragraphs that were also found in a document that you found -- did you find this document on the Internet?
A. I most likely found that on the Internet, yes.
Q. Well, why did that end up in your report?
A. I was cutting and pasting probably to get, you know, background information, and the information that was there was the background information that would make a story to give to the jury about the background information on the pubovaginal sling.
Q. Okay. Did this section and the article that we are talking about have anything to do with the TVT products or suburethral mesh slings?
A. No.

Exh. C, Rosenzweig Dep. 278:1-279:3.

Courts have repeatedly held that expert witnesses are not "permitted to merely read, selectively quote from, or 'regurgitate' the evidence" because a jury is more than capable of reading and summarizing documents on its own. *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009); *see also In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008) ("Having an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony."); *Cf. Cisson*, 2013 U.S. Dist. LEXIS 78061, *139 (permitting experts' factual narrative only "to the extent that they may present the bases for their expert opinions"). Accordingly, Dr. Rosenzweig should not be permitted to regurgitate documents and depositions as purported "expert" testimony.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant its motion and exclude the testimony of Dr. Bruce Rosenzweig in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on December 12, 2013, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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